REMARKS/ARGUMENTS

Claims 1-11 are pending in the instant application. Claims 2-5 and 7-11 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1 and 6 have been amended. Support for these amendments is provided in the specification in claim 6, page 3, lines 1-2, page 7, lines 14-27 and the examples beginning at page 16, line 15.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed August 27, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice claims 2-5 and 7-11 drawn to non-elected subject matter. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Claims 1 and 6

Claims 1 and 6 have been objected to as reciting a non-elected invention. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 1 and 6 to be drawn only to the elected subject matter.

Withdrawal of this objection is respectfully requested in light of these amendments.

III. Rejection of Claims 1 and 6 under 35 U.S.C. § 112, second paragraph

Claims 1 and 6 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that use of the designation CSG is indefinite as the sole means of identifying the claimed polynucleotide. The Examiner also suggests that claims 1 and 6 are indefinite for use of the language "change". In addition, the Examiner suggests that use of the language normal in claim is indefinite as it is not clear what normal is. Finally, the Examiner suggest that use of the language "associated" in claim 1 is indefinite as it is not clear what type of association is referred to.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 1 and 6 to remove the term "CSG" and replace it with --SEQ ID NO:1 or a protein encoded thereby--. Support for this amendment is found in the specification at page 3, lines 1-12 and in originally filed claim

6.

Claim 1 has also been amended to delete the term "change", replacing it with the term "increase". Support for this amendment is provided in the specification at page 7, lines 14-27 and the Examples beginning at page 16, line 15.

In addition, claim 1 has been amended by replacing the phrase "associated with" with the phrase --indicative of--. Support for this amendment is provided in the specification at page 7, lines 14-27 as well.

Applicants respectfully disagree with the Examiner's suggestion that it is not clear what is normal and what is not normal. As mandated by MPEP § 2173.02; definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application; the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. The patent application at page 9, lines 1-6, defines normal human control as a human patient without cancer and/or non cancerous samples from the patient; in the methods for diagnosing or monitoring for metastasis, normal human control may preferably also include samples from a human patient that is determined by reliable methods to have prostate

cancer which has not metastasized. Thus, what is meant by the term "normal" when read in light of the teachings of the application, as required by MPEP 2173.02 is clear and further clarification is not required.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete the term "normal". Support for this amendment is provided in the specification at page 7, lines 14-27 and the examples beginning at page 16, line 15.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the amendments to the claims and the above remarks.

IV. Rejection of Claims 1 and 6 under 35 U.S.C. § 112, second paragraph

Claims 1 and 6 have been rejected under 35 U.S.C.§ 112, first paragraph, as the Examiner suggests that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The Examiner has acknowledged the specification to be enabling for a method for diagnosing the presence of prostate cancer comprising

measuring the mRNA levels of the CSG polynucleotide of SEQ ID NO:1 in prostate tissue, wherein an increase in said level as compared to the non-diseased control tissue is an indication of the presence of prostate cancer. However, the Examiner suggests that the specification does not reasonably provide enablement for a method of diagnosing the presence of prostate cancer comprising measuring the levels of CSG in tissues, wherein a "change" in levels as compared to the normal human control is associated with the presence of cancer.

Thus, in an earnest effort to advance the prosecution of this case, and in accordance with the Examiner's acknowledgment of enabled subject matter, Applicants have amended claim 1 to state that an increase in levels of SEQ ID NO:1 as compared to normal human controls is indicative of prostate cancer.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

Claims 1 and 6 have also been rejected under 35 U.S.C. § 112, first paragraph because the Examiner suggests that the specification is not enabling for diagnosing the presence of prostate cancer in any tissue. The Examiner has acknowledged the specification to be enabling for a method of diagnosing the presence of prostate cancer comprising measuring the mRNA level

of the CSG polynucleotide of SEQ ID NO:1 in prostate tissue. However, the Examiner suggests that the specification discloses that mRNA levels of SEQ ID NO:1 are higher in most cancers. Further, the Examiner suggests that detection of SEQ ID NO:1 in colon tissue would cross react with the known colon cancer antigen disclosed by WO200122920-A2.

Accordingly, claim 1 has been amended to include the term -- relevant-- to indicate which tissues are sampled to determine the presence of prostate cancer.

Additionally, as evidenced by teachings of the specification at page 19, lines 18-21, at the time of filing this application it was well known by those skilled in the art how to design primers and probes specific to each target gene to detect said gene. Thus, limiting the claims to exemplary probes taught in the instant application is not required to enable the instant claimed invention. See MPEP 2164.01.

Withdrawal of these rejections under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

VI. Rejection of Claims 1 and 6 under 35 U.S.C. § 102(a)

Claims 1 and 6 have been rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent 6,177,244, as evidenced by

U.S. Patent 6,287,777. The Examiner suggests that U.S. Patent 6,177,244 teaches detection of overexpression of NPG-1 in a cancerous portion of the prostate wherein NPG-1 is 96% similar to SEQ ID NO:1, from nucleotide 850-1254. Further, the Examiner suggests that U.S. Patent 6,287,777 teaches detection of overexpression of full length NPG-1 in a cancerous portion of the prostate wherein the full length NPG-1 is 98.4% similar to nucleotide 63-1840 of SEQ ID NO:1. Therefore, the Examiner suggests that one would have expected that detection of NPG-1 taught by U.S. Patent 6,177,244 would also detect the claimed SEQ ID NO:1 and that the method of detecting cancer taught by U.S. Patent 6,177,244 seems to be the same as the claimed method.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the priority date of the instant application is October 19, 1998. Accordingly, U.S. Patent 6,177,244, which issued January 23, 2001 is not a valid prior art reference under 35 U.S.C. § 102(a).

Further, to anticipate a claim, a reference must teach every element of the claim. See MPEP § 2131.

Claim 1 has been amended to state that --a 2-fold increase-- is measured in levels of SEQ ID NO:1 or a protein encoded thereby. Support for this amendment is provided in the

specification at page 19, lines 21-27. Neither U.S. Patent 6,177,224 nor U.S. Patent 6,287,777 teaches what degree of expression is indicative of prostate cancer. Accordingly, neither of these references anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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